Registration Decision RD2010-03

Bacillus subtilis strain QST 713

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Registration Decision for *Bacillus subtilis* strain QST 713

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act and Regulations, is granting full registration for the sale and use of *Bacillus subtilis* QST 713 Technical Powder and the following end-use products: Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use, containing the active ingredient *Bacillus subtilis* strain QST 713 to suppress various fungal diseases in asparagus, bushberries, caneberries, bulb vegetables, brassica (cole) crops, cucurbit vegetables, fruiting vegetables, grapes, legume vegetables, leafy vegetables, mint, pome fruits, rutabaga, turnip, radish, strawberries and ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1]: Proposed Registration Decision PRD2009-16- *Bacillus subtilis* strain QST 713. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Bacillus subtilis* strain QST 713 and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2009-16. This decision is consistent with the proposed registration decision stated in PRD2009-16.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2009-16- *Bacillus subtilis* strain QST 713 that contains a detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used, and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (such as children) as well as organisms in the environment (such as those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Bacillus subtilis* strain QST 713?

***Bacillus subtilis* strain QST 713 is a microbial pest control agent used to suppress a number of bacterial and fungal plant pathogens.**

The five end-use products: Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready to Use, are preventative biofungicides that contain *Bacillus subtilis* strain QST 713 as the active ingredient. The five products are intended for different target markets. Serenade MAX and Serenade ASO are for agricultural use, particularly for organic growers. Rhapsody ASO is a product that can be used for organic production of ornamentals. Serenade Garden Concentrate and Serenade Garden Ready to Use are for home and garden use on ornamentals, fruits and vegetables.

Health Considerations

Can Approved Uses of *Bacillus subtilis* strain QST 713 Affect Human Health?

***Bacillus subtilis* strain QST 713 is unlikely to affect your health when Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use are used according to label directions.**

People could be exposed to *Bacillus subtilis* strain QST 713 during handling of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use. When assessing health risks, the PMRA considers several key factors as follows:

- the microorganism's biological properties (for example, production of toxic byproducts);
- reports of any adverse incidents;
- its potential to cause disease or toxicity as determined in toxicological studies; and
- the levels to which people may be exposed relative to exposures already encountered in nature to other strains of the microorganism.

Toxicology studies in laboratory animals describe potential health effects from large doses in order to determine the potential of this organism to cause disease or toxicity. No significant toxicity and no signs of causing disease were observed when *Bacillus subtilis* strain QST 713 was tested on laboratory animals.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for the *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

Bacillus subtilis strains are common in nature, and the use of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use is not expected to significantly increase the natural environmental background levels of this microorganism. Some strains of *Bacillus subtilis* have been isolated from food samples implicated in food poisoning. However, these strains demonstrated the ability to produce a highly heat-stable toxin that may be similar to a toxin produced by *Bacillus cereus*, a known food-borne pathogenic microorganism. *Bacillus subtilis* strain QST 713 is not reported to produce this toxin. Also, no such effects were reported for this microorganism in the United States where it has been registered since 2000. Furthermore, there was no significant toxicity and no signs of causing diseases were observed when *Bacillus subtilis* strain QST 713 was administered orally to rats. Therefore, the establishment of an MRL is not required for *Bacillus subtilis* strain QST 713. In addition, the likelihood of residues of *Bacillus subtilis* strain QST 713 contaminating drinking water supplies is negligible to non-existent. Consequently, dietary exposure and risk are minimal to non-existent.

Occupational Risks From Handling Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use

Occupational risks are not of concern when Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use are used according to label directions, which include protective measures.

Growers handling Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate or Serenade Garden Ready To Use can come into direct contact with *Bacillus subtilis* strain QST 713 on the skin, in the eyes or by inhalation. For this reason, the product labels specify that growers exposed to these end-use products must wear waterproof gloves, long-sleeved shirts, long pants and shoes plus socks. Commercial users must wear a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products) and domestic users should avoid breathing spray mists. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

For the bystander, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When *Bacillus subtilis* strain QST 713 Is Introduced Into the Environment?

Environmental risks are not of concern.

Studies designed to examine the effects of *Bacillus subtilis* strain QST 713 on various non-target organisms were evaluated. No significant adverse effects were observed in birds, freshwater fish, terrestrial arthropods (including honeybees), aquatic invertebrates, marine animals or algae.

Bacillus subtilis is not generally considered to be a disease causing agent. Therefore, Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use are expected to present a negligible risk to non-target organisms.

Value Considerations

What Is the Value of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate, Serenade Garden Ready To Use?

These end-use products contain the active ingredient *Bacillus subtilis* strain QST 713 and are biofungicides that suppress various bacterial and fungal diseases on a number of agricultural crops as well as ornamentals grown indoors, outdoors, in greenhouses, homes and gardens. These products can be used as resistance-management tools because the active ingredient, *Bacillus subtilis* strain QST 713, has a multiple-site mode of action. By rotating their use with other registered chemical fungicides in an integrated pest management program, growers can reduce the possibility of developing resistance among pathogen populations to chemical fungicides as well as potentially reducing the number of applications of chemical fungicides. Serenade MAX, Serenade ASO and Rhapsody ASO can be used in organic vegetable and ornamental production.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions are required by law to be followed.

The key risk-reduction measures on the label of Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use to address the potential risks are as follows.

Key Risk-Reduction Measures

Human Health

As with all microbial pest control products, there are concerns with skin irritation and with users developing allergic reactions through repeated high exposures to *Bacillus subtilis* strain QST 713. Therefore, anyone handling Serenade MAX, Serenade ASO, Rhapsody ASO, Serenade Garden Concentrate and Serenade Garden Ready To Use must wear waterproof gloves, long-sleeved shirts, long pants and shoes plus socks. Commercial users must wear a NIOSH-approved respirator (with any N-95, P-95, R-95 or HE filter for biological products) and domestic users are directed to avoid breathing spray mists. Eye goggles are not required as the eye irritation studies submitted indicated minimal eye irritation potential.

Environment

As a general precaution, handlers are advised not to contaminate irrigation or drinking water or aquatic habitats by cleaning of equipment or by disposing of wastes.

Other Information

1. The relevant test data on which the decision is based (as referenced in this document) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

2. Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the PMRA's website (Requesting a Reconsideration of Decision, healthcanada.gc.ca/pmra) or contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

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[5] As per subsection 35(1) of the *Pest Control Products Act*.

References

A. List of Studies/Information Submitted by Registrant

1.0 Chemistry

PMRA Document Number: 1641783
Reference: 2004, Comparison of Bacillus subtilis QST 713 to Additional Bacillus subtilis Strains by Ribotyping Using the Enzyme PvuII, Data Numbering Code: M2.7.2 Confidential Business Information

PMRA Document Number: 1643517
Reference: 2008, Physico-Chemical Properties of the Formulation Serenade MAX, Data Numbering Code: M2.11 Confidential Business Information

PMRA Document Number: 1643398
Reference: 2007, Data Numbering Code: M2.11

PMRA Document Number: 1643494
Reference: 2007, Serenade Garden Disease Control Ready To Use, Data Numbering Code: M2.11 Confidential Business Information

2.0 Value

PMRA Document Number: 1728698
Reference: 2008, Efficacy of Aqueous and Dried formulations of a Biofungicide (Bacillus subtilis, QRD 141 Serenade Max or QRD 145 Serenade ASO) Against Foliar Diseases of Tomato and Cucumber Under Greenhouse and Field Conditions, Data Numbering Code: 10.2.3.3(D)

PMRA Document Number: 1728697
Reference: Hausbek, M.K. and B.D. Cortright, 2004, Control of diseases of fresh market tomatoes with foliar sprays, 2003, Data Numbering Code: 10.2.3.3(D)

PMRA Document Number: 1728696
Reference: Zitter, T.A. and J.L. Drennan, 2002, Comparing Fungicides for early blight and late blight control in tomato, 2001, F&N Tests 57:V124, Data Numbering Code: 10.2.3.3(D)